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(54) Title: **STENT**

(57) Abstract: Stent especially stent for opening and supporting obstructions in a blood vessel, which stent is made of an alloy comprising at least 90 % by weight of niobium. Preferably the alloy contains other elements selected from the group of Zr, Ti, V, Hf, W, Ta and Mo. The most preferred alloy consists of 98,5 - 99,5 % by weight of niobium and 0,1 - 1,5 % by weight of zirconium.

Stent

The invention relates to a stent, especially a stent for reinforcing a blood vessel wall.

Stents are generally known, and by way of example reference is made to US-A-5628787, US-A-5630840 and EP-A-0873734.

- 5 Up till now a number of metals or metal alloys have been used and/or proposed as basic material for the stent.

In a first type of stent stainless steel has been used especially stainless steel 316 (L, LVM).

One of the problems with this alloy is that it contains nickel, which can lead to unwanted reactions with patients sensitive to this metal, because of the so-called nickel-allergy.

- 10 Otherwise a stent must be clearly visible in a radiography and clearly discernible from its surrounding while being implanted.

This is especially important because the stent must be positioned in the optimal way in order to have the optimal result. Stainless steel does not give a good reflection to X-ray radiation implying that its visibility while being implanted is low and far from optimal.

- 15 In view of these problems with stainless steel it has been proposed to use stainless steel coated with other metals, especially with gold. This has resulted in a better visibility of the stent during implantation, and from that point of view such a stent will have good results.

- 20 Gold-coated stainless steel stent are difficult to make and are relatively expensive. Moreover there might be a problem that the gold layer is not sufficiently adhered to the supporting base material so that locally the coating cracks or flakes off the stent during expansion. Such local removal of the gold coating can result into adverse corrosion effects and free floating of gold particles in the vasculature. Moreover the use of two different metals or metal alloys contacting each other may imply galvanic reactions of which long term clinical effects are unknown, but of which it is suspected that they negatively affect restenosis rates.

- 25 In another stent use is made of tantalum as constructive material for the stent. This has resulted in a reliable stent, but tantalum has the disadvantage that it is too visible in radiographic imaging, to such an extend that it obstructs the imaging of the result of the implantation of such stent.

It is therefore an object of the invention to provide a stent avoiding the above mentioned problems.

This object has been obtained in that the stent is made of an alloy comprising at least 90 % by weight of niobium.

- 5 It has been found that niobium is a metal offering the combination of required characteristics especially with respect to the mechanical and chemical properties and in view of the radiographic imaging.

In a preferred embodiment of the invention the alloy comprise at least 95 % by weight niobium and more preferably at least 98 %.

- 10 Niobium can be combined with a number of other metals in order to obtain the required characteristics.

According to the invention it is preferred that the niobium alloy contains further one or more elements selected from the group of Zr, Ti, V, Hf, W, Ta and Mo.

- Most of these elements, or combinations thereof, improve the mechanical characteristics of the
15 alloy without negatively influencing the biocompatibility with blood or blood vessel systems nor the visibility in radiography.

In the most preferred embodiment of the invention the alloy consists of 98,5 - 99,5 % by weight of niobium and 0,1 - 1,5 % by weight of zirconium.

Claims

1. Stent especially stent for opening and supporting obstructions in a blood vessel, characterized in that it is made of an alloy comprising at least 90 % by weight of niobium
2. Stent according to claim 1, characterized in that it comprises at least 95 % by weight of
5 niobium
3. Stent according to claim 2, characterized in that it comprises at least 98 % by weight of niobium
4. Stent according to anyone of the claims 1-3, characterized in that the alloy further comprises one or more elements selected from the group of Zr, Ti, V, Hf, W, Ta and Mo.
- 10 5. Stent according to claim 4, characterized in that the alloy consists of
98,5 - 99,5 % by weight of niobium and
0,5 - 1,5 % by weight of zirconium

INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, COMPENDEX

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 00 68448 A (DAVITECH INC) 16 November 2000 (2000-11-16) page 1, line 8 -page 8, line 22 claims 1,2,11,17 ---	1-5
A	WO 99 65537 A (STARCK BERND ;MICRO SCIENCE MEDICAL AG (DE)) 23 December 1999 (1999-12-23) page 1, line 25 - line 28 page 3, line 25 - line 29 claims 1,2 ---	1-3
A	US 5 931 867 A (HAINDL HANS) 3 August 1999 (1999-08-03) column 2, line 60 - line 65 claims 1,11 ---	1-3
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 913 871 A (WERNETH RANDELL L ET AL) 22 June 1999 (1999-06-22) column 4, line 4 - line 14 -----</p>	1-3

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0068448	A	16-11-2000	US 6238491 B AU 4498400 A	29-05-2001 21-11-2000
WO 9965537	A	23-12-1999	DE 29810483 U AU 4606199 A	14-10-1999 05-01-2000
US 5931867	A	03-08-1999	DE 19717475 C EP 0873727 A	03-09-1998 28-10-1998
US 5913871	A	22-06-1999	US 6056906 A	02-05-2000